K042583

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 and supports the conclusion of SE for **calc-i-oss** noted below.

1. Applicant's Name and Address:

JUL 1 9 2005

Ultradent Products, Inc.
505 West 10200 South
South Jordan, Utah 84095
Telephone number: 801-553-4200
Fax number: 801-572-0600
Contact Person: Tammy Lavery
RA/QA/QC Senior Manager

2. Name of the Device:

Tradename: calc-i-oss
Common Name: Osteoconductive Bone Void Filler and Synthetic Resorbable Bone Graft Material
Classification: II (21CFR 872.3930)

3. Legally Marketed Predicate Devices to which Equivalence is Claimed:

Predicate Device Identified: Cerasorb Dental (P800035).

Predicate Comparison Table

	calc-i-oss	Legally marketed Cerasorb (Dental)
INDICATIONS:	Indicated for defects after removal of cysts, Augmentation of alveolar crest, possibly in combination with autologous bone and membrane (i.e. guided bond regeneration.) Indicated for apicoectomy and extraction defects in combination with membranes. Indicated for filling of defects after surgical removal of retained teeth Sinus floor elevations and for defects after removal of autologous bone.	Indicated for defects after removal of cysts; repair of marginal and periapical periodontal alveolar bony pockets as well as bifurcations and trifurcations of the teeth; augmentation of the atrophied alveolar ridge; alveolar augmentation of mandibular and maxillary ridges; defects after apicoectomy; and filling bone defects after surgical resection of impacted teeth (without implantation).
CHEMICAL COMPOSITION & PURITY:	> 99% Phase-pure synthetic β-tricalcium phosphate.	> 99% Phase-pure synthetic β-tricalcium phosphate.
FORM:	High purity β-tricalcium phosphate porous spherical granules.	High purity β-tricalcium phosphate porous spherical granules.
PARTICLE SIZE AND RANGE (μm):	Granulate size range from 315 – 1600.	Granulate size range 500-1000.
POROSITY / RESORPTION:	Interconnecting porous material 58% for high level of resorption. Refer to the enclosed Solubility Report for more information on porosity as well as resorption.	Interconnecting porous material 22% for high level of resorption. Refer to the enclosed Solubility Report for more information on porosity as well as resorption.

4. Device Description:

calc-i-oss is a synthetic resorbable osteoconductive bone graft substitute composed of tricalcium phosphate. The device is intended for dental intraosseous, oral, and cranio-/maxillofactial bony defects.

5. Intended Use:

calc-i-oss is indicated for the filling and/or augmentation of intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.

6. Technological Characteristics:

a. Chemical Composition:

calc-i-oss is a granulate consisting of bioresorbable, medical grade beta tri-calcium phosphate and used for the filling of bone defects. (Refer to confidential test reports and data attached.)

b. Physical Properties:

calc-i-oss has a round macrostructure. **Granulate sizes range between 315 and 1600 µm.** calc-i-oss is characterized by a porous and interconnecting microstructure. (Refer to confidential test reports and data attached.)

7. Risk Analysis and Test Methods:

The risks noted below were identified and considered during the design of the product. Testing and/or actions were identified to mitigate each area of possible concern.

Identified Risk	Mitigation
Ineffective Bone Formation	**Material Characterization - See attached confidential test reports and technical data of this submission.**
Adverse Tissue Reaction	**See attached confidential test reports and technical data of this submission. Note: β-TCP is known to be highly biocompatible, resorbable and osteoconductive. Numerous articles on safety and effectiveness are available concerning indications for use in dentistry and are noted in the literature. Mitigation concerning infection is also addressed below.**
Infection	**Sterilization (SAL < 10^{-6}) per ISO 11137. See attached report.**
Improper Use	**Labeling - Refer to the section for labeling and instructional use and warnings.**

8. Substantial Equivalence:

In conclusion and per the review noted above, the calc-i-oss manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, Utah 84095, is substantially equivalent to the legally-marketed device: Cerasorb (Dental) as both of these products are for the most part the same material for same intended use.

Tammy Lavery
RA/QA/QC Senior Manager

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2005

Ms. Tammy Lavery
Regulatory Affairs Senor Manager
Ultradent Product, Incorporated
505 West 10200 South
South Jordan, Utah 84095

Re: K042583
Trade/Device Name: Calc-i-oss
Regulation Number: 21 CFR 872.3930
Regulation Name: Tricalcium phosphate granules for dental bone repair
Regulatory Class: II
Product Code: LPK
Dated: July 6, 2005
Received: July 7, 2005

Dear Ms. Lavery:

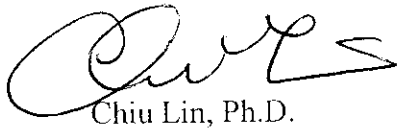
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K042583

510(k) Number (if known): Unknown

Device Name: calc-i-oss

Indications For Use:

Defects after removal of bone cysts,
Periodontal defects in combination with membranes,
Augmentation of alveolar crest, possibly in combination with autologous bone and membrane (Guided Bone Regeneration)
Apicoectomy
Extraction defects in combination with membranes
Defects after surgical removal of retained teeth
Sinus floor elevations
Defects after removal of autologous bone

Prescription Use X **AND/OR** **Over-The-Counter Use**
(Per 21 801 CFR Subpart D) **(Per 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R&Beck DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042583

(Posted November 13, 200